Appendix F

Initiation Visit Report Forms

APPENDIX F. INITIATION VISIT REPORT FORMS

DCP PROJECT
CLINICAL SITE INITIATION VISIT REPORT

I. SITE INFORMATION

Instructions: Please provide the requested information for each of the items listed below. Provide comments whenever necessary or helpful.

Name of Clinical Site:

Protocol Name:

NCI Protocol Number:

Date(s) of Visit:

Conducted by:

DCP Representative(s) Present at the Visit:

Clinical Site Personnel Present at the Visit:

NAME	TITLE	ORGANIZATION	PRESENT AT MEETING
	Principal Investigator		
	Site Coordinator		
	Pharmacist		
	Other		

Additional Comments:

CLINICAL SITE
INITIATION VISIT CHECKLIST

ITEMS VERIFIED and/or DISCUSSED	Y	N	NA	COMMENTS
Background and Purpose of Study				
Study Objectives and Design				
Study Procedures				
Clinical Evaluations				
Laboratory Evaluations				
Schedule of Evaluations				
Specimen Collection, Processing, Storage, and Shipping				
Implications of Missed Evaluations				
Protocol Deviations/Violations				
Toxicity Management				
Protocol Initiation and Enrollment				
Informed Consent Process				
Timing of Pre-Entry Period				
Exemptions				
Randomization or Enrollment				
Recruitment/Retention				
Anticipated Start of Enrollment				
Staff Roles and Responsibilities				
Source Documentation				
Prescriptions				
Agent dispensation				
Informed Consent				
CRF Completion				
Specimen storage				
Randomization				
Regulatory update				
Quarterly Report preparation				
RDC Data Entry and Management				
Adverse Experience Reporting				
AER Guidelines				
Procedures and Forms				
Receipt, Review, and File Investigator's Brochures				
Receipt, Review, and File Package Inserts				
Receipt, Review, and File Safety Reports				

CLINICAL SITE
INITIATION VISIT CHECKLIST (continued)

ITEMS VERIFIED and/or DISCUSSED	Y	N	NA	COMMENTS
Endpoints and Treatment Discontinuation				
Required Evaluations				
Evaluable Participant				
Data Collection				
Procedures				
CRF Completion Guidelines				
Common Errors				
Corrections				
Form Update Procedures				
Plans for Missed Visits				
Disposition of Forms				
CTC Version				
Source Documentation				
What Is Acceptable				
Shadow Files				
Electronic Sources				
Case Report Forms as Source Documents				
Document Retention				
Database Management				
RDC				
Other System to be Used				
Quality Assurance Procedures				
Data Queries				
Staff to Key CRFs and Other Data				
Policy and Procedure Manuals				
DCP Study Site Monitoring Manual				
Other (list under comments)				
Regulatory Documentation Review (Protocol Lead Organization)				
Protocol Signature Page				
IRB/IEC Documentation				
IRB/IEC - Approval Letter				
IRB/IEC-Approved Informed Consent Form				
IRB/IEC-Approved Advertisements				
IRB/IEC-Approved Participant Information Sheets				
Annual Renewal				

CLINICAL SITE
INITIATION VISIT CHECKLIST (continued)

ITEMS VERIFIED and/or DISCUSSED	Y	N	NA	COMMENTS
Amendments				
IRB/IEC Roster				
Assurance Number				
Form 1572				
Financial Disclosure Form				
Laboratory Certification				
Laboratory Normal Ranges				
DHHS and FDA Regulations/GCP Guidelines				
Documentation of IRB/IEC submission of Investigator's Brochures				
Documentation of IRB/IEC submission of Package Inserts				
Documentation of IRB/IEC submission of Safety Reports				
Submission of Data Safety and Monitoring Plans				
Documentation of Human Participants Protection Training				
DCP Reporting Requirements				
Amendments				
Adverse Events Reporting Using NCI CTC				
Case Report Forms				
Progress Reports				
Final Reports				
Recordkeeping Requirements				
Participant Screening Log				
Participant Identification Logbook				
Master Signature Log				
Site Visit Log				
Original Signed Informed Consent Forms				
Source Documents/Confidentiality				
Study-related Correspondence				
Telephone Log				

CLINICAL SITE
INITIATION VISIT CHECKLIST (continued)

ITEMS VERIFIED and/or DISCUSSED	Y	N	NA	COMMENTS
Laboratory Procedures				
Specimen Storage and Disposition				
Shipping Procedures				
Specimen Shipping Log				
Pharmacy				
Dissemination of Information to the Pharmacist				
Drug Storage & Accountability				
Pharmacy Guidelines				
Current Protocol Version				
Documentation of Informed Consents				
Investigator's Brochures				
Package Inserts				
Safety Reports				
Communication				
Quality Assurance Plan				
Communication				
With Westat Personnel				
With DCP Staff				
With CCSA Staff				
With Participating Sites				
Site Monitoring				
Purpose				
Frequency				
Reports				
Site Monitoring at Participating Sites (by Lead Site)				
Conduct of Pharmacy Audit				

ACTION ITEMS IDENTIFIED:

ADDITIONAL COMMENTS/GENERAL IMPRESSIONS OF SITE PERFORMANCE:

Prepared by: Date:

Signature